

Message Text

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PAGE 01 TOKYO 10681 180637Z

ACTION OES-07

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OES/APT/BMP FOR WALSH

DEPT PASS FDA

E.O. 11652: N/A

TAGS: TBIO, JA

SUBJECT: MHW BANS NITROFURAN DERIVATIVES AS CARCINOGENIC

1. ON JULY 6, MINISTRY OF HEALTH AND WELFARE (MHW) BANNED PRODUCTION AND SALE OF NITROFURAN-BASED ANTIBACTERIAL DRUGS AS RECOMMENDED BY CENTRAL PHARMACEUTICAL AFFAIRS COUNCIL, ADVISORY BODY FOR MINISTR OF HEALTH AND WELFARE. REASONS FOR PROHIBITION GIVEN BY THE COUNCIL AREA THAT THE DRUGS ARE CARCINOGENIC AND THAT THERE ARE OTHER SAFER ANTIBACTERIAL DRUGS CURRENTLY AVAILABLE ON MARKET.

2. BAN WAS PUT ON 49 VARIETIES OF SUCH DRUGS USING SIX NITROFURAN DERIVATIVES--ACETYLFURATRIZINE, DIHYDROXYMETHYLFURATRIZINE, DIFURAZONE, GUANOFURACIN, FURAZOLIDONE, NITROFURAZONE. RAT TESTS CONDUCTED BY NARA MEDICAL COLLEGE HAVE SHOWN THAT THESE NITROFURAN DERIVATIVES COULD CAUSE CANCER OF DIGESTIVE ORGANS.

3. COUNCIL ALSO RECOMMENDED BAN OR LIMITED USE OF 16 OTHER DRUGS BECAUSE OF THEIR POTENTIALLY UNDESIRABLE EFFECTS. THEY INCLUDE HYPOTENSIVE DRUGS, OPHTHALMICS, UNCLASSIFIED

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ANTIPHLOGISTICS, AND PSYCHOTROPIC MEDICINES.

4. THE BANNED DRUGS ARE AMONG THE 1,245 DRUGS SUBJECTED TO THE COUNCIL'S 12TH DRUG ASSESSMENT PROGRAM JUST COMPLETED. THE COUNCIL STARTED DRUG REASSESSMENT IN 1971 AND THUS FAR 60 PERCENT OF THE DRUGS ON THE JAPANESE MARKET HAVE BEEN REASSESSED.

5. MHW'S PHARMACEUTICAL AFFAIRS BUREAU WILL REPORT
ITS ACTIONS ON DRUGS TO WORLD HEALTH ORGANIZATION
AND U.S. FOOD AND DRUG ADMINISTRATION DIRECTLY.
MANSFIELD

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